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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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28107 7590 10/26/2010  
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EXAMINER

WHITE, DENNIS MICHAEL

ART UNIT

PAPER NUMBER

1772

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/552,752	KRETSCHMANN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DENNIS M. WHITE	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 25,28-39,42-45 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25,28-39,42-45 and 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/20/2010 has been entered. Claims 25, 28-39, 42-44, 47-48 are amended. Claim 27 is cancelled. Claims 49-50 are new. Currently claims 25, 28-39, 42-45, 47-50 are pending.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 recites the limitation, "an openable closure positioned over the opening." It is unclear as to the metes and bounds of the claims. Is the applicant claiming the openable closure over the second opening? Or the first opening? For the prosecution of claim 38, the office is reading the limitation as a film that does covers the second opening.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25, 28-39, 42-44, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Imburgia (USP 5,750,184).

Regarding claim 25, 34-35, and 47, Imburgia teaches a biological indicators for monitoring a sterilization cycle (“sterilization testing apparatus”) comprising a biological indicator 10 (“housing”) including a pathway 30 (“channel”) comprising cavity 122 and 120 (“testing chamber having a base portion”), at the end of a tortuous path 36 (“supply line for supplying a sterilizing medium to the testing chamber” “base portion of the test chamber is formed at the end of the supply line”) (Fig. 2, col. 6 lines 37-47), an indicator to produce a color change of the growth medium (“at least one indicator located in at least the testing chamber for indicating completion of sterilization”) (col. 10 lines 14-24) that can be seen because the first member 16 and second member 18 (“the housing being comprised of an assembly of at least two superimposed parts”) are clear (“second housing part comprises a transparent material providing visual inspection of the indicator without opening the housing”), the tortuous path 36 (“supply line”) being comprised of a pathway (“channel”) formed by the first and second members 16, 18 such as where the first member 16 has a channel 36a formed in a serpentine shape (“in at least one of the housing parts”) (col. 6 lines 19-24), the pathway (“channel”) having

Art Unit: 1772

an opening at one end thereof communicating with the testing chamber and an opening 32 at the other end thereof for communicating with a source of the sterilizing medium outside the housing (Fig. 2) ("a sterilization medium that enters the housing through the opening travels directly to the testing chamber via the channel"). The first and second member do not share a common edge or surface prior to being superimposed (Fig. 1). Imburgia teaches the channel 36a is formed in first member 16 (Fig. 2) ("supply line"). The channel is defined by the sides ("ridges") of the first member 16 and the bottom of second member 18 ("inwardly facing ridge"). Fig. 5 shows that the channels can be defined by a plurality of sides, some being located at the outer side of the first housing part and some being interior of the first housing part (Fig. 5). ("supply line being comprised of a channel located between a sidewall of the first housing part and at least one ridge positioned on the interior of the first housing part, the sidewall being located at an outer side of the first housing part, the channel providing a flow path for a sterilizing medium defined by the sidewall and the at least one ridge" "a plurality of ridged is formed on the first housing part). It is noted that the second member 18 is a flat surface on the side facing the first member 16 (Fig. 1) ("the second housing part is provided with a flat surface on a side facing the first housing part"). Imburgia teaches if the biological indicator is contemplated for use in a sterilization process requiring elevated temperatures, then the plastic will be selected from those materials having higher melting points, such as polycarbonate (col. 5 lines 30-34) ("housing parts fabricated of injection-moldable plastic" "having a heat resistance of at least 121 degrees C). Imburgia teaches a tortuous path with a length that covers the entire surface not

Art Unit: 1772

covered by the testing chamber and ending at the test chamber ("the channel extending over substantially the entire surface of the first housing part, but for a surface portion of the first housing part, comprising the testing chamber" "channel communicating with the testing chamber at a channel end opposite the opening in the first housing part, whereby a sterilizing medium that enters the housing through the opening travels directly to the testing chamber via the channel"). It is noted that no length is specified, therefore the "length of the supply line relative to cross-section thereof is sufficiently great to prevent complete deaeration of the supply line during sterilization" is sufficiently broad to read on any length of the channel.

Regarding claim 28, Imburgia teaches the indicator is in the growth medium which is present in the pathway 30 ("a single indicator which extends over the entire length of the supply channel") (col. 10 lines 14-24).

Regarding claim 29 Imburgia teaches the indicator in the growth media and another indicator 44 distributed over the entire channel 30 (Fig. 2: 44 and 30) ("a plurality of indicators are distributed over the entire length of the channel").

Regarding claims 30, 33, Imburgia teaches the device is sealed by RF sealing ("apart from said opening, the housing is hermetically sealed" "first and second housing parts are fixedly secured together") (Abstract, col. 9 lines 41-46).

Regarding claim 31, Imburgia teaches the pathway ("channel") has parallel side edges (Fig. 2: 36) and is shown to have a uniform depth ("of square or rectangular cross-section") (Fig. 3: 36a).

Art Unit: 1772

Regarding claim 32, Imburgia teaches the pathway 30 comprises a tortuous path 36 ("the channel provides a spiral or meandering flowpath") (Fig. 2).

Regarding claims 36, 38-39, Imburgia teaches perforations ("second opening") 50, 150, 160, and 170 in the device 100 (Fig. 4 and 7) ("a breaking line along which the first and second housing parts are manually breakable" "a second opening provided in the second housing part for accessing the indicator"). The perforations would provide access to the indicator in the pathway 30 if the perforations are torn because the indicator is taught being provided in the pathway (col. 3 lines 3-5). The perforations are covered by the label 40 that is capable of closing the perforation ("the second opening being provided with an openable closure positioned over the opening" "film for re-closing the second opening")

Regarding claim 37, Imburgia teaches flap 48 formed of both the first and second housing parts. The flap is capable of being torn and would provide access to the indicator (Fig. 4) ("at least one tear strip in the at least one of the first and second housing parts, whereby tearing away of the tear strip provides access to the indicator") (col. 8 lines 59-66).

Regarding claim 42, Imurgia teach a chemical indicator 44 that is useful to indicate when the biological indicator 10 has been exposed to sterilizing conditions. ("scale" is sufficiently broad to read on any standard of measurement) applied by label 40 to member 18 ("applied to at least one of the housing parts") (col. 7 lines 30-32)

Regarding claim 43, Imburgia teach the device 10 ("housing") is comprised of label 40, first and second member 16 and 18, ("first, second, and third superposed

Art Unit: 1772

housing parts”) and the pathway 30 (“channel”) is comprised of tortuous path 36 situated between the first and second members. (“in which at least the second housing part is provided with a channel that is superimposed and in communication with the channel of the first housing part”)

Regarding claim 44, Imburgia teach a user can separate one or more individual units of the assemblage 100 before use by the perforations 170 (“housing parts are detachable from each other”) (col. and the second member 18 is then placed into contact with (for example, is lowered onto) first member 16 and adhered thereto, by conventional techniques, such as heat sealing or adhesive bonding. Examples of heat sealing include sealing through use of heated rollers, sealing through use of heated bars, radio frequency sealing, and ultrasonic sealing (“further comprising a seal positioned between the first and second housing parts that seals the channel off from the external environment”) (col.5 line60-col. 6 line 3).

Regarding claim 47, Imurgia teach the device is made by the method for molding the first member to create cavities 20, 22 is through the use of a thermoforming process where materials are heated and then drawn or pushed into an appropriately shaped die using a vacuum or over-pressure. On contacting the die, the material cools and retains its new shape. (“the housing parts comprise at least one injection molded heat-resistant plastic”) (col. 5 lines 40-46).

6. Claims 45, 48, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imburgia (USP 5,750,184) in view of Browne (WO 01/56618 A1).



Art Unit: 1772

Regarding claims 45, 48, and 50, Imburgia teaches a biological indicators for monitoring a sterilization cycle ("sterilization testing apparatus") comprising a biological indicator 10 ("housing") including a pathway 30 ("channel") comprising cavity 122 and 120 ("testing chamber having a base portion"), at the end of a tortuous path 36 ("supply line for supplying a sterilizing medium to the testing chamber" "base portion of the test chamber is formed at the end of the supply line") (Fig. 2, col. 6 lines 37-47), an indicator to produce a color change of the growth medium ("at least one indicator located in at least the testing chamber for indicating completion of sterilization") (col. 10 lines 14-24) that can be seen because the first member 16 and second member 18 ("the housing being comprised of an assembly of at least two superimposed parts") are clear ("second housing part comprises a transparent material providing visual inspection of the indicator without opening the housing"), the tortuous path 36 ("supply line") being comprised of a pathway ("channel") formed by the first and second members 16, 18 such as where the first member 16 has a channel 36a formed in a serpentine shape ("in at least one of the housing parts") (col. 6 lines 19-24), the pathway ("channel") having an opening at one end thereof communicating with the testing chamber and an opening 32 at the other end thereof for communicating with a source of the sterilizing medium outside the housing (Fig. 2) ("a sterilization medium that enters the housing through the opening travels directly to the testing chamber via the channel"). The first and second member do not share a common edge or surface prior to being superimposed (Fig. 1). Imburgia teaches the channel 36a is formed in first member 16 (Fig. 2) ("supply line"). The channel is defined by the sides ("ridges") of the first member 16 and the bottom of

Art Unit: 1772

second member 18. Fig. 5 shows that the channels can be defined by a plurality of sides, some being located at the outer side of the first housing part and some being interior of the first housing part (Fig. 5). ("supply line being comprised of a channel located between a sidewall of the first housing part and at least one ridge positioned on the interior of the first housing part, the sidewall being located at an outer side of the first housing part, the channel providing a flow path for a sterilizing medium defined by the sidewall and the at least one ridge" "a plurality of ridged is formed on the first housing part). It is noted that the second member 18 is a flat surface on the side facing the first member 16 (Fig. 1) ("the second housing part is provided with a flat surface on a side facing the first housing part"). Imurgia teach if the biological indicator is contemplated for use in a sterilization process requiring elevated temperatures, then the plastic will be selected from those materials having higher melting points, such as polycarbonate (col. 5 lines 30-34) ("housing parts fabricated of injection-moldable plastic" "having a heat resistance of at least 121 degrees C). Imurgia teaches a tortuous path with a length that covers the entire surface not covered by the testing chamber and ending at the test chamber ("the channel extending over substantially the entire surface of the first housing part, but for a surface portion of the first housing part, comprising the testing chamber" "channel communicating with the testing chamber at a channel end opposite the opening in the first housing part, whereby a sterilizing medium that enters the housing through the opening travels directly to the testing chamber via the channel"). It is noted that no length is specified, therefore the "length of the supply line relative to cross-section thereof is sufficiently great to prevent complete deaeration

Art Unit: 1772

of the supply line during sterilization” is sufficiently broad to read on any length of the channel. Imburgia teach the sealing of the first and second member can be heat sealing or adhesive sealing.

Imburgia is silent about the seal comprises a mat and the channel is positioned between the sidewall provided on the outer side of the first housing part, the at least one inwardly facing ridge provided on the second housing part, and the at least one inwardly facing ridge of the first housing part.

Browne teaches a re-usable sterilization device comprising at least two parts which are releasably connected together. Browne teaches the separable components having grooves brought together during the connection of the components to define respective channels with the intermediate compressible member (“seal comprising a mat”) allows for easy cleaning and airing of the grooved means. Hence, the device according to the invention can be both readily aired and cleaned while nevertheless being re-usable. (Pg. 11 lines 1-7). The tortuous path is formed between the grooves 46 (“at least one inwardly facing ridge of the first housing part”) and sidewall of component 32 (“the sidewall provided on the outer side of the first housing part”) and a ridge (Fig. 1 at 28) and skirt 26 of cap 10 (“at least one inwardly facing ridge provided on the second housing part) of component 26 provided on component 36 (“an outer side of the first housing part”). The compressible member provides a seal to create the tortuous path that sealingly divides the primary chamber into two secondary chambers (Pg. 7, para. 2 and Pg. 9 para. 2). It is desirable to provide an intermediate compressible member for sealing while providing a re-usable sterilization device.

Art Unit: 1772

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art, as motivated by Browne, to substitute the adhesive seal of Imburgia with the intermediate compressible member of Browne because they are known sealing members to seal the device components together with the added advantage of allowing for the cleaning and airing of the device so it can be reused.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art, as motivated by Browne, to substitute the flat second housing member with the cap 10 that has a ridge and a skirt of Browne because they are known housing members that contain a tortuous path in a sterilization indicator and it provides the above advantage of further sealing off the tortuous path by having a ridge and a skirt that interconnects with the grooves of the tortuous path.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imburgia (USP 5,750,184) in view of Browne (WO 01/56618 A1) and further in view of McCormick et al (USP 5,824,553).

Imburgia teaches the limitations of claim 25 as per above.

Regarding claim 49. Imburgia teach the sealing of the first and second member can be heat sealing or adhesive sealing. Imburgia is silent about the seal comprises a mat and the second member is box-shaped, having an open side positioned between a top surface and a bottom surface of the second housing part, the first housing part being inserted into the second housing part through the open side, whereby the first

Art Unit: 1772

housing part is retained within the second housing part, the opening of the first housing part being positioned along the open side of the second housing part, a sealing mat positioned between a top surface of the first housing part and a bottom of the top surface of the second housing part, whereby the mat provides a seal between the first and second housing parts.

Browne teaches a re-usable sterilization device comprising at least two parts which are releasably connected together. Browne teaches the separable components having grooves brought together during the connection of the components to define respective channels with the intermediate compressible member ("seal comprising a mat" ") allows for easy cleaning and airing of the grooved means. Hence, the device according to the invention can be both readily aired and cleaned while nevertheless being re-usable. (Pg. 11 lines 1-7). The compressible member provides a seal to create the tortuous path that sealingly divides the primary chamber into two secondary chambers (Pg. 7, para. 2 and Pg. 9 para. 2). It is desirable to provide an intermediate compressible member for sealing while providing a re-usable sterilization device.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art, as motivated by Browne, to substitute the adhesive seal of Imburgia with the intermediate compressible member of Browne because they are known sealing members to seal the device components together with the added advantage of allowing for the cleaning and airing of the device so it can be reused.

Art Unit: 1772

McCormick et al teach a structure for evaluating the efficacy of sterilization apparatus using either steam or ethylene oxide as sterilant is disclosed. The structure includes an insert of porous material having a cavity formed therethrough for retaining a biological or chemical indicator. The insert of porous material and indicator are enclosed within an outer covering box 26 made of relatively impervious plastic to provide restricted pathways to air and sterilant. (Abstract and col. 4 line 8-12) ("second member is box-shaped, having an open side positioned between a top surface and a bottom surface of the second housing part, the first housing part being inserted into the second housing part through the open side, whereby the first housing part is retained within the second housing part"). The outer covering is provided with removable portions which are removed when the structure is used to evaluate ethylene oxide sterilization ("the opening of the first housing part being positioned along the open side of the second housing part")(Abstract). The box 26 may be configured with foldable end flaps 28 and 30 at opposing ends of the box and tabs 40 that may be removed to enlarge the existing entryway. This provides the advantage of being able to control the amount of sterilant that enters the device.

Simple substitution of one known element for another to obtain predictable results is held to be obvious. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the outer covering box of McCormick et al for the second member of Imburgia because it is a well known sturdy plastic housing to contain a sterilization indicator with a tortuous path and it provides the above advantage of being able to control the amount of sterilant that enters the device.

***Response to Arguments***

8. Applicant's arguments with respect to claims 48-50 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 5/20/2010 have been fully considered but they are not persuasive.

10. Applicants argue that the channel in Imburgia is relatively small relative to the overall housing surface, does not teach channel dearation, and therefore does not meet the limitation in claim 25. It is noted that the claim requires that the channel extend over substantially the entire surface of the first housing part, but for a surface portion of the first housing part comprising the test chamber. The Imburgia channel does meet the claim because it covers substantially all the housing part that is not covered by the test chamber as required by the claim and therefore depending on the sterilization liquid, dearation is possibly not complete along the path. In the absence of better defining the actual length of the channel, the channel length required can be read on any length that is capable of incomplete dearation and covers the length not covered by the test chamber.

11. Regarding claim 45, Applicants argue that the seal in Brown does not seal off the external environment. It is noted that the intermediate member in Brown does sealingly close the tortuous path formed by the grooves between the two components 36 and 32 (Pg. 9 Para. 3-4). Further, Applicants argue that because the sterilizer insert is not provided with an opening on the outside of the housing, the combination is not proper because Brown teach away from the invention claimed. It is noted that the steam

Art Unit: 1772

enters at one end and exits at the other. Within the device, after passing through the tortuous path, the sterilization liquid reaches the indicator. It is argued that the medium fluid in Brown flows from the inside-out. The argument is not convincing because as shown in Fig. 1 in Brown, the sterilization medium enters the device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571) 270-3747. The examiner can normally be reached on Monday-Thursday, EST 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571) 272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Application/Control Number: 10/552,752

Page 16

Art Unit: 1772

/LYLE A ALEXANDER/

Primary Examiner, Art Unit 1773

/dmw/